UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION) CASE NO. 1:17-MD-2804
OPIATE LITIGATION	
) SPECIAL MASTER COHEN
THIS DOCUMENT RELATES TO:)
"Track One Cases")
	ORDER REGARDING
	DISCOVERY FROM
	THE FEDERAL GOVERNMENT

Various defendants have engaged with certain federal agencies – including the Department of Justice ("DOJ"), the Drug Enforcement Agency ("DEA"), and the Federal Bureau of Investigation ("FBI") – seeking certain discovery to support their defenses to plaintiffs' claims. To a large extent, these federal agencies have refused to produce the requested discovery. Accordingly, the defendants seek rulings from the undersigned compelling production. The defendants and the agencies submitted position papers and also offered oral argument during various teleconferences. Having considered the parties' submissions, the Special Master now rules as follows.

Agenda Item 222 - Rite Aid's Motion to Compel Production By DEA/DOJ.

Every so often, the DEA conducts an audit of Rite Aid Mid-Atlantic's Drug Distribution Center to ensure, among other things, that physical security and record-keeping at the Center are adequate and appropriate. Over a year ago, Rite Aid served upon DOJ a subpoena seeking the

production of documents related to these audits, and also the deposition of Donald Tush, a DEA Diversion Investigator who conducted some of the audits. DOJ refused, so Rite Aid filed a motion to compel. The parties submitted lengthy position papers and presented oral argument at teleconferences. Because Rite Aid was not a defendant in the Track One-A trial, the undersigned did not immediately rule on the motion; but Rite Aid is a trial defendant in Track One-B, so the time has come for a ruling.

In response to Rite Aid's subpoena, DOJ interposed the following defenses. For the reasons set forth below, the Special Master concludes these defenses are largely unfounded.

A. Procedural Deficiencies.

DOJ first asserts Rite Aid did not follow proper procedures when it subpoenaed the documents and testimony it seeks. As Rite Aid correctly notes, however, DOJ points to technicalities that: (1) DOJ waived, or (2) it would be futile for the Court to require Rite Aid to fulfill. For example, DOJ observes that, although Rite Aid served its subpoena on Investigator Tush and also sent a copy to AUSA James Bennett, together with a *Touhy* request, Rite Aid did not serve the subpoena on the DEA. DOJ insists Rite Aid must serve its subpoena on DEA before it can seek to compel production. But in its letter to AUSA Bennett, Rite Aid specifically wrote: "Because this

¹ Specifically, DOJ refused to produce: (i) completed audit documents of the Distribution Center; and (ii) documents regarding Rite Aid's compliance with 21 U.S.C. §823 and 21 C.F.R. §1301.74, which address diversion controls and suspicious order monitoring.

Rite Aid also originally requested from DOJ documents regarding (iii) DEA's interpretation, enforcement, and practices related to 21 U.S.C. §823 and 21 C.F.R. §1301.74, and (iv) guidance and communications provided by DEA to Rite Aid regarding the criteria for what makes an order for controlled substances "suspicious." Following discovery, Rite Aid does not seek to compel production of these "category iii and iv" documents.

subpoena is directed at a DEA employee, compliance is subject to the *Touhy* process, and for that reason we have not affected formal service of process and hope that it will be unnecessary." Letter from Kelly Moore to Special Master at 2 (June 25, 2019) ("*Second Moore Letter*") (quoting letter from Scott Schutte to James Bennett at 1 (Jan. 25, 2019)). In the many months since, including during meet-and-confers to discuss narrowing of Rite Aid's requests and a mediated resolution, DOJ did not contend Rite Aid needed to complete formal service, nor that is should have subpoenaed DEA in addition to Investigator Tush. Moreover, it would be futile to require Rite Aid now to serve another, formal subpoena seeking discovery the DEA has already refused to produce. Accordingly, the DEA's procedural objections are overruled.

B. Relevance and Burden.

DOJ asserts Rite Aid "can neither establish that its requests are proportional to the burden [on DOJ] nor show that it has a compelling interest sufficient to overcome [DOJ's] *Touhy* denial." Letter from Natalie Waites to Special Master at 2 (June 20, 2019) ("*First Waites Letter*"). DOJ adds that Rite Aid's request "lacks specificity," and the documents requested have "no meaningful nexus [to] the parties' claims and defenses." *Id*.

As an initial matter, this MDL Court earlier stated, in a similar context, that it will "examine[] the DEA's objections under the standard set out in Fed. R. Civ. P. 45(d)." *Order Regarding ARCOS Data* at 9 (docket no. 233). Further, the MDL Court adopted the view that "district courts should apply the federal rules of discovery when deciding on discovery requests made against government agencies." *Id.* (quoting *Exxon Shipping Co. v. U.S. Dep't of Interior*, 34 F.3d 774, 780 (9th Cir. 1994)). Accordingly, the undersigned examines whether the discovery Rite

Aid seeks is "relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(1). The DOJ is incorrect that Rite Aid must show a "compelling interest" to overcome *Touhy* and obtain the discovery it seeks.

DOJ asserts in conclusory fashion that Rite Aid's requested discovery has "minimal relevance" to the issues raised in the MDL, *First Waites Letter* at 2, but there is little question that the requested documents and testimony are highly germane. For example, immediately after the DEA's unannounced July 2012 audit of Rite Aid's Distribution Center, Rite Aid employees summarized what occurred in a short memo, including that "Both DEA inspectors are very impressed and pleased to see that Rite Aid demonstrates its due diligence by having an excellent excessive order monitoring program." The adequacy of Rite Aid's suspicious order monitoring system ("SOMS") is at the very center of the issues to be decided during the upcoming trial in Track One-B, and DEA's assessment of the adequacy of Rite Aid's SOMS could not be more relevant. Discovery of the DEA audit documents and Investigator Tush's testimony are certainly "important ... in resolving the issues." Fed. R. Civ. P. 26(b)(1).

DOJ next argues that Rite Aid's request would impose a disproportionate burden on the government. DOJ asserts that, "Given the minimal value of the DEA's scheduled investigation

² Letter from Kelly Moore to Special Master, Exh. C. at 6 (June 14, 2019) ("First Moore Letter"). This contemporaneous 2012 written statement by Rite Aid also calls into question DOJ's 2019 assertion that DEA's audits only "focused on the [Distribution Center's] physical security and record-keeping and simply do not speak to the design or functionality of Rite Aid's [SOMS]." First Waites Letter at 3.

reports and of Tush's testimony, the burden of producing this information outweighs any benefit to Rite Aid." *First Waites Letter* at 4. As noted, however, the requested discovery is certainly not of "minimal value" to Rite Aid; just the opposite. DOJ also insists Rite Aid does not need the requested discovery because Rite Aid's own documents, such as the short memo quoted above, provide the same information. But there is no comparison in evidentiary value between a document written by Rite Aid itself and a document written by the federal Agency that oversees compliance with the Controlled Substances Act.

Moreover, DOJ/DEA has already identified and reviewed for privilege most (if not all) of the requested documents. Indeed, DOJ/DEA was able to produce exemplar audits to the undersigned for *in camera* inspection (for reasons explained below) in fairly short order, undercutting their complaint that even locating the documents would be difficult and time-consuming. And Rite Aid seeks deposition of only one witness. DOJ has not shown that Rite Aid's request is disproportionate or imposes an excessive burden.

DOJ offers one final "slippery slope" argument, positing that granting Rite Aid's motion to compel will lead to similar requests from other defendants: "compelling production here could lay the groundwork for myriad requests for similar documents from other parties during the Track Two and subsequent discovery phases, multiplying the already disproportionate burden placed on the DEA, and further siphoning resources from the DEA's critical mission, which is to detect and prevent diversion." *First Waites Letter* at 4. As discussed in footnote 3 below, however, this Order compels DOJ to locate and produce just six audit documents to Rite Aid. Even multiplied by numerous MDL distributor defendants, this is not an onerous burden. This topic is addressed further below, under Agenda Item 226.

In any event, all of DOJ's arguments regarding burden and relevance are conclusory or incorrect, and the slippery slope argument is of no more avail. The substantial need Rite Aid has demonstrated for the requested discovery, to defend itself in this national litigation, is certainly not disproportional to the burden placed on DOJ to produce it.

C. Vagueness.

DOJ writes that, "In demanding documents related to 'Rite Aid Mid-Atlantic's compliance with 21 U.S.C. § 823 and 21 C.F.R. § 1301.74,' Rite Aid's request is so vague as to be meaningless. In fact, the only specific documents that Rite Aid has identified that may be responsive to this request are the completed audits of the Distribution Center." *First Waites Letter* at 3. DOJ thus concludes Rite Aid is merely engaged in a "fishing expedition." *Id*.

DOJ is correct that Rite Aid has focused on obtaining documents connected with four DEA audits of Rite Aid's Distribution Center, which took place in 2005, 2009, 2012, and 2014. Rite Aid is clearly entitled to all of those audits. But it is unfair to contend Rite Aid is simply fishing for other documents without basis. During teleconferences and in letters, Rite Aid explained it also seeks documents associated with these audits, including "contemporaneous DEA documents such as notes and summaries." *First Moore Letter* at 2. Rite Aid is entitled to any such documents as well, if they exist.³

³ DOJ provided to the Special Master for *in camera* inspection six documents: a single "Report of Investigation" (using DEA Form 6) for the 2005 and 2009 audits, and two such Reports each for the 2012 and 2014 audits. Rite Aid is entitled to production of these six Reports. Rite Aid suggests it also wants other documents or communications clearly related to the audits, such as notes, summaries, check-lists, or other communications. It appears that the Reports of Investigation already contain all of the investigators' notes, summaries, check-lists, and so on. But if such documents exist separately, DOJ must produce them.

That said, the Special Master agrees that Rite Aid's request for any other "DEA records of Rite Aid Mid-Atlantic's compliance with regulations" is vague. DOJ need not search for or produce such documents.

D. Privilege.

DOJ initially asserted that the documents Rite Aid seeks are all protected from discovery by both the deliberative process privilege and the law enforcement privilege. DOJ later dropped its assertion of deliberative process privilege. The Special Master finds DOJ's assertion of the law enforcement privilege is not well-taken, although minor redactions of documents will be allowed.

DOJ asserts that DEA's audit documents "reveal investigative methods," including the following "key investigative decisions" made by DEA: (1) times and durations of investigations, (2) the number of substances audited, (3) the types of substances investigated, (4) the types of records examined, (5) the components of physical security most important to investigators, and (6) the types of intelligence collected from facility operators. DOJ asserts that "distributors armed with this information could undermine the DEA's enforcement efforts." *First Waites Letter* at 6.

But this assertion is clearly hyperbolic: it is hard to imagine a distributor can somehow avoid detection of its bad acts because it knows that unannounced investigations begin at 9:00 a.m., or last for eight hours, or focus on opioids. More to the point, Rite Aid (and other opioid distributors) already know all of the above-listed information. Rite Aid's Distribution Center employees worked with and responded to DEA investigators during the entire course of the audit – the DEA's Reports of Investigation document the names of the employees that answered the door, met with investigators, retrieved requested data, provided copies of documents, and answered investigators'

questions. Thus, "[i]n the very process of performing the inspection, DEA discloses, either explicitly or implicitly, each of these very items." *Second Moore Letter* at 5.

Out of an abundance of caution, the Special Master asked for and received from DOJ the six audit documents at issue. *In camera* inspection reveals that production of the audits will not lead to "disclosure of law enforcement techniques and procedures, [undermine] the confidentiality of sources, [endanger] witness and law enforcement personnel, [invade] the privacy of individuals involved in an investigation, [or] otherwise . . . interfer[e] with an[y] investigation." *MacNamara* v. *City of New York*, 249 F.R.D. 70, 78 (S.D.N.Y. 2008). Accordingly, production of the audits is not protected by law enforcement privilege.

DOJ reasonably requests, however, that, if the motion to compel is granted, it be allowed to redact from the "Indexing" section of each document personal identifying information (such as social security numbers, DEA numbers, dates of birth, and addresses), as well as the case number. These redactions are allowed.

E. Investigator Tush.

DOJ notes that Investigator Tush was involved only with the 2005 and 2012 audits of Rite Aid's Distribution Center. Accordingly, DOJ asks that, if the motion to compel is granted, the deposition of Tush be less than the seven hours normally allowed under Fed. R. Civ. P. 30(d)(1). The Special Master agrees that less time should be sufficient. Rite Aid's deposition of Tush will be limited to 3.5 hours.

Agenda Item 226

DOJ was correct that Rite Aid was not the only MDL defendant that wanted DEA audits of distribution centers. After Rite Aid and DOJ submitted their position papers to the Special Master (discussed above), the MDL defendants as a group sent DOJ a list of a total of 31 distribution centers for which they also wanted DEA audit documents. *See* exhibit 1.

DOJ's position on this group request closely mirrored its stance regarding Rite Aid; indeed, much of the language in DOJ's submission on the group request is identical to its Rite Aid submissions. The only meaningful difference in DOJ's submission on the group request has to do with burden. DOJ explained:

[T]he Defendants seek DEA-6 reports for 31 facilities related to Track One. DEA has reached out to the 26 field offices that are responsible for maintaining the records of the scheduled investigations for those facilities to ascertain where the records are located and the resources required to collect, review, redact, and produce them. DEA has determined that there are 492 documents responsive to the Defendants' request that is the subject of this motion to compel. * * * Accordingly, DEA estimates that Defendants' request would require DEA to collect, review, and redact approximately 9,800 to 14,700 pages.

Letter from Natalie Waites to Special Master at 3 (Aug. 9, 2019) ("Second Waites Letter"). DOJ added that many of these audits must be retrieved from archives, and some of "these reports disclose potential targets of investigation, witness information, and the identity of confidential sources." *Id.*

The Special Master is sympathetic to the DOJ's burden argument and therefore mitigates it as follows.

First, DOJ need not produce at this time all of the requested audits. The defendants who produced the group list are as follows:

Pharmacy Defendants	Manufacturer and Distributor Defendants
Discount Drug Mart	Prescription Supply
CVS	H.D. Smith
HBC - Giant Eagle	McKesson
Walmart	AmerisourceBergen
Walgreens	Cardinal
Rite Aid	Allergan
	Anda

Currently, only the six Pharmacy Defendants are scheduled for trial before the MDL Court. The Distributor Defendants recently asserted the Special Master does not have jurisdiction to resolve discovery disputes involving them – even though they are currently scheduled for trial in a transferor court following remand by this MDL Court, and even though they submitted briefs on the discovery issues to the Special Master before remand – because their upcoming trial is not pending in the Northern District of Ohio. Until this jurisdictional question is addressed by the MDL Court, the undersigned will withhold ruling on their motion to compel audits from DOJ. Accordingly, the Special Master does not impose upon DOJ at this time the burden of retrieving or producing audit documents for any of the Manufacturer or Distributor Defendants. That represents half of the distribution centers on the defendants' group list.

Regarding the Pharmacy Defendants, however, DOJ must produce the requested audits, for all of the reasons explained above under Agenda Item 222. (The distribution centers for which audits must be produced are highlighted in yellow on exhibit 1.) DOJ may redact "potential targets

of investigation, witness information, and the identity of confidential sources," to the extent such

information is present in these audits. DOJ may also redact from the "Indexing" section of each

document any personal identifying information and the case number.

Finally, in light of the burden imposed upon DOJ, and especially because this burden is

likely compounded by the current coronavirus pandemic, DOJ may "roll out" this discovery

production. DOJ should begin by producing Rite Aid's audit documents and then produce other

documents for other pharmacy defendants as soon as it is reasonably able to do so.

Agenda Item 223

Various defendants submitted to the FBI Touhy requests for certain documents and

depositions. The FBI declined to produce any discovery. Accordingly, the defendants ask the

Special Master to compel production.

It is not entirely clear which defendants submitted these requests to the FBI, but it appears

they are mostly (if not entirely) Manufacturer and Distributor Defendants - not Pharmacy

Defendants. Accordingly, for the same jurisdictional reason stated above, the Special Master will

not rule on the defendants' request to compel production from the FBI at this juncture.

IT IS SO ORDERED.

/s/ David R. Cohen

DAVID R. COHEN

SPECIAL MASTER

Dated: April 10, 2020

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